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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,341	05/03/2002	Michael R. Hayden	SMAR-0013	8795

7590 04/20/2004

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EXAMINER	
SULLIVAN, DANIEL M	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,341	HAYDEN ET AL.	
	Examiner	Art Unit	
	Daniel M Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 35-57 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 35-57 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 35-39, 42 and 51, drawn to a method of treating an LPL-responsive disease in a subject comprising administering an LPL S447X therapeutic, wherein the LPL S447X therapeutic is a polypeptide.

Group II, claim(s) 35-41 and 43-51, drawn to a method of treating an LPL-responsive disease in a subject comprising administering an LPL S447X therapeutic, wherein the LPL S447X therapeutic is a nucleic acid.

Group III, claim(s) 52-57, drawn to a gene therapy vector comprising a nucleic acid encoding an LPL S447X protein.

Claims 36 and 37 are further restricted to a single LPL-responsive disease. An election to prosecute Groups I or II should include an election of a single disease from claims 36 or 37.

The inventions listed as Groups I-III and the methods limited to treating various specific LPL-responsive diseases do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

PCT Rule 13.2 requires that unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-III and the methods of treating various LPL-responsive diseases do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The shared same or corresponding technical feature that unites the groups is the treatment of an LPL-responsive disease comprising administering an LPL S447X therapeutic. An LPL S447X therapeutic is defined, *inter alia*, in the first full paragraph on page 3 of the specification as encompassing modifications, derivatives and analogs of LPL S447X peptides. As the native LPL enzyme would reasonably meet the definition of an LPL S447X peptide modification, derivative or analog, the therapeutic of the claims encompasses LPL. Hayden *et al.* (WO 96/11276) discloses a method of treating an LPL-responsive disease comprising

administering an LPL S447X therapeutic (*i.e.*, a gene therapy vector capable of expressing LPL; see especially the discussion beginning the second full paragraph on page 11 and continued through page 12). As the corresponding technical feature is not a contribution over the art, the identified groups do not relate to a single general inventive concept.

The special technical feature of Group I is the administration of an LPL S447X polypeptide, which is not shared by the other groups.

The special technical feature of Group II is the administration of an LPL S447X encoding nucleic acid, which is not shared by the other groups.

The special technical feature of Group III is a product or composition comprising a nucleic acid encoding an LPL S447X protein, which feature is not shared by the other groups.

Finally, each of the LPL-responsive diseases set forth in claims 36 and 37 have distinct etiology and progression which, absent evidence or clear admission to the contrary, would dictate unique method steps not comprised in the method of treating other LPL-responsive diseases.

Accordingly, Groups I-III and methods limited to treating various specific LPL-responsive diseases are not so linked by the same or a corresponding special technical feature as to for a single general inventive concept.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DMS

DAVID GUZO
PRIMARY EXAMINER